

# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Addiese: COMMISSIONER FOR PATENTS P O Box 1450 Alexandra, Virginia 22313-1450 www.wepto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/542,043	09/15/2005	Charles R. Cantor	701586-53653	8687
50187 7590 11/20/2008 RONALD I. EISENSTEIN		EXAMINER		
NIXON PEABODY LLP			KAPUSHOC, STEPHEN THOMAS	
100 SUMMER BOSTON, MA			ART UNIT	PAPER NUMBER
			1634	
			MAIL DATE	DELIVERY MODE
			11/20/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

# Advisory Action Before the Filing of an Appeal Brief

	Application No.	Applicant(s)		
10/542,043		CANTOR ET AL.		
Examiner		Art Unit		
	Stephen Kapushoc	1634		

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 21 October 2008 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

- 1. X The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
  - a) The period for reply expires 3 months from the mailing date of the final rejection.
  - The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### NOTICE OF APPEAL

2. The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

## **AMENDMENTS**

- 3. The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because (a) They raise new issues that would require further consideration and/or search (see NOTE below);
  (b) They raise the issue of new matter (see NOTE below);

  - (c) They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for
  - appeal; and/or (d) They present additional claims without canceling a corresponding number of finally rejected claims.
  - NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)).
- 4. The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
- Applicant's reply has overcome the following rejection(s): See Continuation Sheet. 6. Newly proposed or amended claim(s) would be allowable if submitted in a separate, timely filed amendment canceling the
- non-allowable claim(s). 7. X For purposes of appeal, the proposed amendment(s): a) will not be entered, or b) X will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
  - The status of the claim(s) is (or will be) as follows:
  - Claim(s) allowed: none.
  - Claim(s) objected to: none
  - Claim(s) rejected: 1-23.
  - Claim(s) withdrawn from consideration: none.

#### AFFIDAVIT OR OTHER EVIDENCE

- 8. The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
- 9. The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
- 10. The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

## REQUEST FOR RECONSIDERATION/OTHER

- 11. X The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
- Note the attached Information Disclosure Statement(s), (PTO/SB/08) Paper No(s). 13. Other:
- /Jehanne Sitton/

Primary Examiner

/Stephen Kapushoc/ Examiner, Art Unit 1634

1634

Continuation of 5. Applicant's reply has overcome the following rejection(s):

The rejections of claims 1-8 and 19-24 under 35 USC 112 second paragraph, as indefinite, as set forth on pages 3-4 of the Office Action of 07/23/2008 are withdrawn in light of the amendments to the claims and the cancellation of claim 24. The rejection of claim 24 under 35 USC 103 as set forth on page 4 of the Office Action of 07/23/2008 is withdrawn in light of the cancellation of claim 24.

Continuation of 11, does NOT place the application in condition for allowance because:

Applicants' amendments to the claims and Remarks of 10/21/2008 have been fully and carefully considered but are not found to be persuasive to put the application into condition for allowance. It is noted that the limitation previously recited in dependent claim 24 (now cancelled, previously dependent from claim 1) has been amended into independent claims 1, 9, 12, and 17. The limitation requires that three primer pairs each flark a nucleic acid region of about 100 bo long.

Initially Applicants appear to argue that the recited limitation provides an unexpected result of 'an extremely high efficiency for haplotyping' as indicated in par, [0077] of the specification. However, par, [0077] of the specification recites that:

High PCR efficiency is mainly due to the high efficiency of amplification of very short amplicons (typically 100 bp) and the high sensitivity of MALDI-TOF mass

spectrometric detection of DNA oligonucleotides.

Thus the specification teaches that the result, asserted to be unexpected by Applicants, requires both amplification of a short amplicon and MALD-TDF analysis. As such, the claims, which require only that 'each primer pair flanks a nucleic acid region that is about 100 bp long' is not commensurate with the requirements for the asserted unexpected results (see MPEP 716.02(d) because the claims do not require MALD-TDF analysis.

Further, while par [0077] of the specification teaches high efficiency amplification of very short amplicons (typically 100 bp); the claims require only that primer pairs flank a nucleic acid region of about 100 bp long. Thus the claims require only primer pairs that can amplify an amplicon comprising about 100 bp, and do not in fact require a step of amplification of an amplicon that is 100 bp or less in length (i.e. the term 'flanks' requires only that the primer pairs surrounds the recited 'about 100 bp', and does not require an amplicon consisting of about 100 bp'.

With further regard to the asserted unexpected results, it is noted that par [0077] of the specification provides that a single reaction allows of 40-45% haplotyping efficiency. The cited prior art of Furlong at al (1993) provides for high efficiency of allele analysis (Table 3 on p. 1197), indicating that even with the amplification of amplicons between 149 and 266 bp in length in a multiplex reaction, the efficiencies disclosed by the instant specification are not, in fact, unexpected.

As such the Examiner maintains that the claimed methods are obvious in view of the teachings of the prior art as cited in the rejections of the previous Office Action of 7/23/2008, and the amended claims of 10/21/2008 remain rejected for the reasons of record as set forth in the Office Action of 07/23/2008.